

Speakers



Walid El Azab
Steris Corporation,
Belgium



Werner Hofstetter
Octapharma, Austria



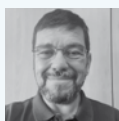
Arjan Langen
GE Healthcare,
The Netherlands



Carsten Moschner
Dastex, Germany



Inga Marie Schlägl
Bayer, Germany



Axel Schroeder
Concept Heidelberg,
Germany



Robert Schwarz
FH Campus Vienna,
Austria



Wolf-Dieter Wanner
Germany

Contamination Control

Requirements, Measures and Strategy



Live Online Training from 09 - 11 November 2022



Highlights

- Regulatory Requirements, incl. Annex 1
- Principles of Hygiene and Microbiology
- Disinfectants: Characteristics, Selection and Qualification
- Sources of Contamination and Preventive Measures
- Microbiological Monitoring and Trending
- Risk Management
- Handling of OOS Results
- Cleanroom Garment and Single Use Consumables
- Hygiene of Personnel and Training of Operators
- CCS – a Dynamic System

This course will provide practice-oriented guidance and includes case studies

Objective

In most cases the implementation of appropriate hygiene programmes and measures have been implemented as an essential part for the manufacturing of pharmaceutical products. A series of regulations address the subject of microbiological facility control but GMP requirements are mostly described in more general terms. But how can they be introduced in pharmaceutical companies in a practice-oriented way? What is state-of-the-art? How should detergents and disinfectants be used?

The overall goal of such a system is to prevent microbiological contamination of the pharmaceutical product. But even if such a system has been established, it is of utmost importance that these programmes and measures are understood and followed by all operators who carry out quality-relevant work. Therefore, regulations demand intensive training in hygiene issues.

Against the background of these requirements, this Live Online Training is designed to cover all important aspects of controlling microbiological contamination. It ranges from sources of contamination to validation of cleaning and disinfection processes and training of operators. A focus will be on those problems that occur frequently in pharmaceutical production; possible solutions to these challenges will be discussed.

The course ranges from regulatory requirements and microbiological basics, sources of contamination, hygiene measures and monitoring to life cycle management of the overall strategy.

Background

The lack of control of microbiological contamination is an outstanding integral part of inspection findings. Not all authorities regularly publish overviews or inspection results, but if one looks at the available data of the last 20 years from various inspection authorities, the following picture emerges:

Between 1995 – 2005, the potential risk of microbiological contamination was the No 2 Critical GMP Deficiency and the No 1 Major GMP Deficiency observed during inspections requested by the CHMP/CVMP of EMEA.

MHRA's review of the deficiencies 2011/2012 issued 57 deficiencies related to personnel as well as 75 contaminations by chemical/physical and microbial causes.

In 2018 and 2019, Annex 1 was the second most frequently mentioned annex of the GMP Guide when it came to deviations in MHRA inspections.

A permanent high number of FDA warning letters with microbiological deviations or issues in cleaning and contamination control:

Fiscal Year 2016 – 23 WL

Fiscal Year 2017 – 24 WL

Fiscal Year 2018 – 16 WL

Fiscal Year 2019 – 32 WL

Fiscal Year 2020 – 25 WL

Fiscal Year 2021 – 36 WL

This actual state clearly demonstrates the importance to concern oneself with this topic in detail.

In pharmaceutical manufacture, cleaning and disinfection measures are important and decisive process steps for fulfilling the quality requirements on the medicinal product. To carry them out properly, personnel needs to be both qualified and motivated.

All national and international pharmaceutical GMP regulations - especially those on sterile manufacturing - call for cleaning and hygiene programmes in the pharmaceutical companies.

Target Audience

People who are involved in

- Microbial monitoring
- Implementation of hygiene programmes
- Selection and qualification of disinfectants
- Handling of microbial deviations
- Training of operators for monitoring

Moderator

Axel H. Schroeder, Concept Heidelberg

Programme

Module 1: Regulatory Requirements and Background

Basic Principles of Microbiology, Hygiene and Contamination Control

- Microorganisms
 - Microbial growth
 - Characteristics
 - Sources
- Basic hygienic actions
- Cleaning/disinfecting/sterilization
- Way of contamination

Regulatory Requirements

- General regulatory requirements and guidelines
- Prevention of contamination and cross contamination
- Requirements for validation
- ISO standards
- Quality Risk Management

Sources of Contamination and Preventive Measures

- Sources of contamination throughout the facility
- HVAC
- Water
- Raw materials and packaging components
- Personnel and clothing

Effective Training of Operators

- Regulatory requirements (EU-GMP, FDA Guidelines, experiences from inspections)
- Methods and tools
- Measurement and documentation of training success
- Practical approaches

Module 2: Monitoring and Control Strategies

Microbiological Monitoring

- Monitoring of non-sterile processes
- Aseptic manufacture:
 - developing a programme
 - interpreting data
 - regulatory requirements
- Monitoring methods, air, surface, people
- A complete programme for a sterile product

Microbiological Control of Water Systems

- Water as raw material
- Contamination sources within the water system
- Technical aspects
- Control methods
- Microbiological testing of water

Trending of Environmental Monitoring Data

- How do you do it?
- What do the results really tell you?
- How should you react on the results?

Module 3: Cleaning/Disinfection – Measures, Pit Falls, Deviation Handling

Cleaning and Disinfection of Surfaces

- Criteria of selection of disinfectants
- Rotation of antimicrobial substances considering their chemical interaction
- Cleaning potential of disinfectants
- Users acceptance

Qualification of Disinfectants

- Different gassing systems
- Guidance documents, standards and regulatory requirements
- Basis for qualification
- Case study for qualification of disinfectants
- Efficacy – how to control?

Hygiene of Personnel – Cleanroom Behaviour

- Contamination from personnel
 - Classic employee deviance
 - Gowning procedure
 - Hand disinfection

Case Study: Managing Disinfection Programmes

- Hygiene programme
- Cleanroom concept
- Demands on environment, equipment and personnel
- Cleaning and disinfection concept

Case Studies: Disinfections Issues

- Practical examples of microbial deviations after cleaning and disinfection activities
- Root causes and pitfalls
- Measures for troubleshooting in practice
- Preventive measures to avoid errors

Handling of Microbiological OOS/OOL Results

- Failure investigation,
- Following corrective actions and preventive actions

Module 4: Further Challenges – Garment, Single-Use Consumables and More

Cleanroom Garment, Requirements, Selection and Laundering

- Different fabrics and their characteristics like filtration capacity and wearing comfort
- Garment systems oriented by the cleanroom class
- Requirements on decontamination and laundering
- Outsourcing

Validation of a Decontamination System for Production Equipment, Process Devices and Cleanrooms

- Technical requirements & background
- Qualification of a fogging system
- Validation of a fogging process

Cleanroom Consumables - a so called „Cent Product“ but with Consequences

- Definition of cleanroom consumable products
- The impact during the daily application
- How is that reflected in guidelines?

Module 5: Overarching Considerations of Importance

Quality Risk Management

- Risk Assessment:
 - Risk Identification
 - Risk Analysis
 - Risk Evaluation
- Risk Management

Contamination Control Strategy - An Interdisciplinary and Dynamic System

- Formulate a CCS
- Implement a CCS and develop a strategic plan to make the strategy work as intended by mapping/designing the organisational structure, procedures, control processes, distributing resources, developing the decision-making processes, etc.
- Evaluate the CCS efficiency to ensure process performance and product quality while improving the CCS level over time

Your Benefit: Internationally Acknowledged Certificate from ECA Academy

The EU GMP Guide requires: „... All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training,...“. This is why you receive an acknowledged participant certificate, which lists the contents of the seminar in detail and with which you document your training.





Date of the Live Online Training

Wednesday, 09 November 2022, 09.00 h – 18.00 h CET

Thursday, 10 November 2022, 08.30 h – 18.00 h CET

Friday, 11 November 2022, 08.30 h – 13.30 h CET

Technical Requirements

We use WebEx Events for our live online training courses and webinars. At <https://www.gmp-compliance.org/training/online-training-technical-information> you will find all the information you need to participate in our trainings and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate, plus VAT)

ECA Members € 1,890

APIC Members € 1,990

Non-ECA Members € 2,090

EU GMP Inspectorates € 1,045

The fee is payable in advance after receipt of invoice.

Registration

Via the attached reservation form, by e-mail or by fax message.

Or you register online at www.gmp-compliance.org.

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

Conference language

The official conference language will be English.

Ordering Recordings

We also offer many of the training courses and conferences as recordings. This means that you can watch the videos of the event „on demand“ – whenever it suits you – on our web server. It is quite uncomplicated and doesn't require any software – you simply watch the video on your browser. You can find all recorded events at www.gmp-compliance.org/recordings.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.

CONCEPT HEIDELBERG

P.O.Box 10 17 64

69007 Heidelberg, Germany

Phone +49(0)62 21/84 44-0

Fax +49(0)62 21/84 44 34

info@concept-heidelberg.de

www.concept-heidelberg.de

For questions regarding content please contact:

Mr Axel H. Schroeder (Operations Director) at

+49(0)62 21/84 44 10, or at

schroeder@concept-heidelberg.de

For questions regarding organisation please contact:

Ms Isabell Helm (Organisation Manager) at

+49(0)62 21/84 44 49, or at

helm@concept-heidelberg.de

Speakers

Walid El Azab, STERIS Corporation, Belgium

Walid El Azab is a Technical Services Manager for the Life Sciences Division of STERIS Corporation. He currently provides technical support related to cleaning chemistries, disinfectants and sterility assurance products and their application and validation. Walid has held various positions including Project Manager, Inspection Readiness Manager, Quality and Regulatory Manager, and Qualified Person (QP).

Werner Hofstetter, Octapharma GmbH, Austria

Since 2002, Werner Hofstetter is working at the pharmaceutical production of Octapharma Pharmazeutika GmbH, Vienna and is, among other things, responsible for validation of disinfectants and the cleanroom monitoring. Since 2006 he is head of aseptic production at Octapharma.

Arjan Langen, Director Sterility Assurance, GE Healthcare, The Netherlands

Arjan Langen has over 20 years of experience within the field of pharmaceutical microbiology. He worked for several pharmaceutical and biotech companies (Nobilon, DSM, MSD) and had various local and global roles within QC, QA, manufacturing and auditing. Currently he is a Director Sterility Assurance at GE Healthcare, responsible for the global Sterility Assurance program.

Carsten Moschner, CEO Dastex GmbH & Co. KG, Germany

Currently, Carsten Moschner is CEO of Dastex with a focus on research and development as well as optimising of textile cleanroom garment. Carsten is a member of several expert committees, e.g. deeply involved in the new VDI 2083 chapter about the suitability of cleanroom equipment.

Dr Inga Marie Schlägl, Bayer - GP Grenzach Produktions GmbH, Germany

Inga Marie worked until 2013 at the clinical research Center in Freiburg. 2014 she joined Bayer as GMP Compliance Manager. In her current position, she is leading the department for monitoring and media.

Axel H. Schroeder, Concept Heidelberg, Germany

Axel Schroeder worked in different positions with responsibilities in contamination control for Henkel, Ecolab and Basan. Since 2008 he is operation director at Concept Heidelberg for microbiology and biotechnology.

Robert Schwarz, University of Applied Sciences, FH Campus Vienna, Austria

Robert Schwarz joined Baxter in 2001 as coordinator of environmental monitoring. From 2005 he was validation specialist responsible for equipment qualification, sterilisation validation and cleaning validation. Since 2010 he is university lecturer in the field of biotech at the University of Applied Sciences in Vienna.

Wolf-Dieter Wanner, Germany

Wolf-Dieter Wanner started working in an independent pharmacy and later joined Henkel Hygiene (later part of Ecolab). There he integrated the German cleanroom business with Adams Healthcare and Shield Medicare into an international contamination control team focusing on pharmaceutical aseptic manufacturing. Since 2011 he has been working as a freelance consultant.

If the bill-to-address deviates from the specifications on the right, please fill out here:

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)



Contamination Control – Requirements, Measures and Strategy, Live Online Training from 09 - 11 November 2022

Title, first name, surname

Department

Company

Important: Please indicate your company's VAT ID Number

Purchase Order Number, if applicable

City

ZIP Code

Country

Phone / Fax

E-Mail (Please fill in)

General terms and conditions

If you cannot attend the conference you have two options:

1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees:
 - Cancellation until 4 weeks prior to the conference 10 %,
 - Cancellation until 3 weeks prior to the conference 25 %,
 - Cancellation until 2 weeks prior to the conference 50 %,
 - Cancellation within 2 weeks prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event. If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.

Terms of payment: Payable without deductions within 10 days after receipt of invoice.

Important: This is a binding registration and above fees are due in case of can-

cellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message.

In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed!) (As of January 2012).

German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.